Summary of Safety and Effectiveness Information
[510(k) Summary]

SYNTHES (U.S.A.)
1690 Russell Road
Paoli, PA 19301

(610) 647-9700
Contact: Jonathan Gilbert
6/16/00

DEVICE
Synthes CerviFix System consists of rods, plate/rods, hooks, clamps, screws, nuts and transconnectors. The implants are composed of the titanium alloy Ti6Al7Nb (ASTM F1295) or commercially pure grade 4 Titanium (ASTM F67).

INDICATIONS
Hooks, Plate/Rods, Rods and Screws
When intended to promote fusion of the cervical spine and occipitocervical junction (occiput-T3), the plate/rod, rod, hook and screw (3.2 mm cortex, 3.5 mm and 4.0 mm cancellous) components of the Synthes *CerviFix*™ System are indicating for the following:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- spondylolisthesis
- spinal stenosis
- fracture/dislocation
- atlantoaxial fracture with instability
- occipitocervical dislocation
- revision of previous cervical spine surgery
- tumors

When used to treat these cervical and occipitocervical conditions, these screws are limited to occipital fixation only.

Hooks and Rods
The rod and hook components are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Rods, Clamps, Screws and Nuts
The rods, clamps, screws and nuts are intended to promote fusion following reduction of fracture/dislocation or trauma in the upper thoracic spine (T1-T3).

The use of these screws (3.5 mm, 4.0 mm cancellous and 3.5 mm, 4.2 mm cortex) is limited to placement in T1-T3 in treating thoracic conditions only. They are not intended to be placed in or treat conditions involving the cervical spine.

The Synthes *CerviFix*™ System can also be linked to the Synthes Universal Spinal System using the 3.5 mm/6.0 mm parallel connectors from that system, and via the CerviFix tapered rods using lamina hooks, transverse process hooks, pedicle hooks, 4.2 mm screws, and the 5.0 mm/ 6.0 mm parallel connector.

CLASSIFICATION:
The classification of the CerviFix System is Class II, as per the Code of Federal Regulations, Title 21, Section 888.3050: Appliance, Fixation, Spinal, Interlaminal and Section 888.3060: Spinal intervertebral body fixation orthosis. The product code is KWP. The Panel code is 87.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The components of the Synthes CerviFix system are similar to the components of previously cleared spinal systems. Pre-clinical testing shows the biomechanical performance of the subject device to be similar to the performance of previously cleared spinal systems with similar indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 9 2001

Mr. Jonathan Gilbert
Senior Regulatory Affairs Associate
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301

Re: K011969
Trade Name: Synthes CerviFix™ System
Regulatory Number: 888.3050
Regulatory Class: Class II
Product Code: KWP
Dated: June 22, 2001
Received: June 25, 2001

Dear Mr. Gilbert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General Restorative
And Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011969.

Device Name: **Synthes CerviFix System**

Indications for Use:

Hooks, Plate/Rods, Rods and Screws

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use ____ (Per 21 CFR 801.109)

(Division Sign-Off)

Division of General, Restorative and Neurological Devices

510(k) Number K011969